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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,284	07/14/2003	Gennadiy Yershov	ANL-IN-01-052b	8247
7590 Joan Pennington Unit 1804 535 North Michigan Avenue Chicago, IL 60611			EXAMINER SODERQUIST, ARLEN	
			ART UNIT	PAPER NUMBER
			1743	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

5

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,284	<b>Applicant(s)</b> YERSHOV ET AL.	
	<b>Examiner</b> Arlen Soderquist	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-24 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-14-03</u> . | 6) <input type="checkbox"/> Other: ____  |

1. The disclosure is objected to because of the following informalities: the status of the parent application needs to be updated.

Appropriate correction is required.

2. The use of the trademark VELCRO has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 23 the use of the trademark VELCRO causes the claim to be indefinite since a trademark is used to identify the maker of a product not a product. In other words a trademark does not define a structure but rather identifies a maker of a product. As such the product structure can change even though the trademark remains the same.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (US 5,831,763) in view of Carter (US 4,608,344) or Herron (US 5,677,196) and Hauser (US 4,159,875), Staunton (US 3,705,048) or Sillman (US 2003/0203492). In the patent Meyer teaches a system to obtain a high resolution image of a relatively large sample (11) for viewing

Art Unit: 1743

by a researcher includes a rectangular holder (20) that receives a microscope slide (10) and which includes a glass filter (40) that reduces the amount of illumination of the sample without reducing the Kelvin light temperature, and a scanner (22) that receives the holder (20) and produces electrical signals which are fed to the hard drive of a computer (23) where a high resolution image of the sample is displayed on the monitor (24). One embodiment of the invention (FIGS. 5-8) utilizes a separate high intensity light source (60A) for the scanner (22A) for illuminating opposed surfaces of the slide (10A), and a fiber optic light pipe (66A) connects the high intensity light source to the holder (20A) within the scanner (22A). Column 1, lines 49-63, teach that microscope specimen slides that are viewed through a microscope usually are made of glass and commonly are rectangular having side dimensions of 1 inch x 3 inches. The thickness dimension is 1.1 mm. A sample of histological tissue is prepared and sliced to a very thin section (3 to 5 microns), which is mounted on the glass slide and protected by a rectangular coverslip that has dimensions of 40 mm long x 20 mm wide x 0.15 mm thick. Such slides are viewed by pathologists, anatomists and biologists and the like on a daily, routine basis. Indeed literally millions of such slides are created and viewed by thousands of researchers and clinicians every day, so that improvements in accordance with this invention have wide application in the art. Column 2, lines 15-19 teach that an object of the invention is to provide such a system in which a separate high intensity light source is transmitted to the slide holder for illuminating opposed sides of the slide to permit visual observation of unstained samples. Figures 5-5 show this embodiment and the holder used. These figures show a separate high intensity light source (60A) for attachment to the scanner (22A) to illuminate the slide (10A) retained by the holder (20A). The light source is a fiber optic illuminator including a high intensity quartz halogen projection bulb, an on-off switch (62A), and a rheostat (64A). A fiber optic light pipe (66A) extends from illuminator and is bifurcated into two branches (68A) for extending to opposite sides (72A) of the scanner. Each fiber optic branch has an end fiber optic bundle (70A) that appears to fan out near the slide. An outer protective sheath is provided for each branch. A fiber optic illuminator which has been found to be satisfactory is sold under the name Intralux 6000 by Volpi Manufacturing, USA of Auburn, N.Y. Each side of the scanner has an elongate slot (74A) therein sized and arranged to receive the fiber optic bundle for insertion within the scanner for connection to a holder (20A). Side walls (26A,27A) of the holder are formed with slots (76A)

Art Unit: 1743

that communicate with a pocket (35A) and rectangular viewing window (31A). The rectangular specimen slide is received within the pocket and is supported on the bottom (41A) of the pocket. The slots are sized and arranged to receive the fiber optic bundles in a releasable press fit.

Column 5, lines 23-60 teach the operation of the device and modifications that are within the scope of the invention. Particularly relevant is the use of this embodiment to produce darkfield illumination of the sample and the definition of the term "sample to include sections, specimens, and other materials that can be secured to a microscope slide. Meyer does not teach a bioarray on the slide or plastic springs as part of the holder for positioning the slide in the optical system.

In figures 13a to 17 the patent Carter teaches a waveguide device waveguide plate (41) held by brackets (not shown) and a counter plate (42) maintained in accurately controlled parallel facing relationship in respect of the wave-guide. The waveguide plate can be made of high quality float glass or quartz. The counter plate can be a microscope slide. The uses a light source (43, in this particular embodiment, the light source is a He-Ne laser providing polarized light) and an optical train to provide the light to an edge of the waveguide plate. A detector (53) is arranged to collect scattered light in figures 13b. A detector (73) for collecting fluorescent light is shown in figure 16. Figure 14 shows an array or pattern alternating zones of higher and lower affinity for proteins (antigens or antibodies). Figure 15 shows a perfectly flat and regular surface (41c) of a waveguide was sprayed with microdroplets of antibody (AB) and, during analysis, the antigen AG attaches only to such preferential areas.

In the patent Herron teaches methods and apparatus for evanescent light fluoroimmunoassays. The apparatus employs a planar waveguide with an integral semi-cylindrical lens, and has multi-analyte features and calibration features, along with improved evanescent field intensity. A preferred embodiment of the biosensor and assay method have patches of capture molecules each specific for a different analyte disposed adjacent within a single reservoir (bioarray). The capture molecules are immobilized to the patches on the waveguide surface by site-specific coupling of thiol groups on the capture molecules to photo-affinity crosslinkers which in turn are coupled to the waveguide surface or to a non-specific-binding-resistant coating on the surface. The patches of different antibodies are produced by selectively irradiating a portion of the waveguide surface during the process of coupling the photo-affinity crosslinkers the selective irradiation involving a mask, a laser light source, or the

Art Unit: 1743

like. Column 6, lines 16-30 teach the waveguide (122) being a microscope slide or coverslip made from glass, quartz or plastic and the edge illumination of the waveguide. The same column teaches an imaging detector (150) being CCD device or an array of detectors. columns 3-4 teach needs that the device is meant to fulfill.

In the patent Hauser teaches a specimen slide holder suitable for use in an automated instrument. The holder is molded plastic. Column 1, lines 29-32 teach that a specimen holder which is suitable for use with an automated analytical instrument must hold the specimen in proper orientation or position for analysis within the particular instrument. Figures 1-5 show the molded plastic slide holder (10) in conjunction with a glass slide (20). The slide holder generally includes a carrier frame (11) surrounding or encompassing an opening or window (12). The holder is provided with integral slide holding means composed of a pair of projections (14a,14b), a spring (13a,13b), a backing support (16) and a projection or lip (15) which cooperate together to hold the glass slide in proper position. As best shown in figure 2, the glass slide is held in position with the backing support abutting the edges of the bottom of the slide, while the lip and projections overlap and abut portions of the top of the slide. The integral spring is biased to urge the slide in the direction of the lip.

In the patent Staunton teaches a clinical spinner that includes a slide holder (4) to which a slide is clamped. Figure 4-5 show the holder detail. A microscope slide (6), 25 x 75 x 1 mm. is retained by spring clips (5) mounted on either end of the holder. The clip may be integrally molded with the holder from resilient plastic material. Side tabs (11) and end stops (13) are provided to locate the slide on the holder.

In the published application Sillman teaches a holder for bioarrays (a planar substrate and an array of chemical moieties on a surface of the substrate). The holder may include a body with a retaining mechanism which releasably retains an array unit in a seated position. The biopolymer arrays are DNA or protein arrays, which are useful in diagnostic, screening, gene expression analysis, and other applications. Paragraph [0006] teaches the arrays being scanned to detect the results of the analysis. Paragraph [0009] teaches that different holders place the array substrate at different spatial locations which causes trouble when scanning the array in a scanner. Figure 4-7 show the holder and include a body with two opposed side portions (14) and a channel (18) positioned therebetween. The side portions have respective side edges (14a). The

Art Unit: 1743

channel has a bottom surface (32) which acts as a backer member, and has a closed leading end (26a) and an open trailing end (26b). Opposed sides (20) of the channel have ledges (22) running the length of the sides. Portions of the ledges act as a movable set of rear clamp members. Four tabs (30) positioned about the channel, have outside portions (34) attached to side portions 14 and inside portions (36) which extend over the ledges and are slightly spaced therefrom in a normal position of the ledges. The inside portions act as a front set of fixed clamp members which are fixed to side portions 14. Positioned outside the channel on a front side of the holder, is a control member set of buttons (40), each of which is positioned and movable within an opening (15) in a front surface (16) of a corresponding side portion (14). Each control member is connected to the channel (including ledges 22) such that moving the control members rearward (into the page, as viewed in figure 4) causes the channel 18 to also move rearward, thereby moving the ledges (portions of which, beneath inside portions 36 of tabs 30, act as the rear clamp member set) away from portions 36 of the tabs (which act as the fixed front clamp member set) to an open position. That is, pressing down on the buttons moves the clamp member sets to an open position. Four springs (72, seen in figure 9) resiliently urge the channel and hence the ledges forward toward one another (thereby urging the rear clamp member, composed of portions of the ledges, to the normal position). Paragraph [0049] teach how the slide is retained in a seated position within the holder, thus helping to ensure that the array is in a known fixed position relative to the holder for reading of the array. Paragraph [0050] teaches that the holder is preferably made in three molded sections from a plastic material.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used bioarrays as taught by Carter, Herron or Sillman in the device of Meyer because of the ability of the Meyer device to illuminate an edge of the waveguide/slide substrate that has material attached thereto and scan/image the resulting scatter/fluorescence which is required for analysis of the Carter, Herron and Sillman arrays. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate spring structures as taught by Hauser, Staunton or Sillman into the holder of Meyer because of the ability to hold a slide in a defined location within the holder as taught by Hauser, Staunton or Sillman.

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer in view of Carter or Herron and Hauser, Staunton or Sillman as applied to claim 19 above, and further in

view of Kurtz (US 5,671,084). Meyer does not teach a diffuser separating the optical fiber fan faces from the edge of the substrate.

In the patent Kurtz teaches a line illumination system. The illuminator includes a light source which produces a light beam; an optical condenser between the lamp and the film gate to condense and shape the beam; and optics adapted to diffuse and direct the light beam so as to produce a uniform line of controlled diffuse illumination at the film gate. The optics uses an integrating diffuser to transform the light so that the line of light at the film gate will have a substantially uniform intensity profile. Figure 15 shows a fiber optic circle to line converter (52, substantially similar to the fiber ends 70A of Meyer). The fiber optic circle-to-line converter may reduce the burden on the lensing system. The light would be focused onto a circular input face, and then coupled into the bundled fibers. Within the device, the fibers would be randomized, or reorganized in a structured way, such that at the output end, there is a line of light with a much more uniform profile than the input light. Typically, these converters can provide macro-uniformity, but micro- non-uniformity as is shown in the plot accompanying FIG. 12. This micro-non-uniformity can be as much as 50%. An integrating diffuser could then be used to enhance the uniformity at the film gate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a diffuser as taught by Kurtz into the light illuminating optical fiber device of Meyer because of the ability to produce a more uniform illumination by reducing the micro-non-uniformity as taught by Kurtz.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer in view of Carter or Herron and Hauser, Staunton or Sillman as applied to claim 19 above, and further in view of Gerrans (US 4,977,725). Meyer does not teach the slide supported on a VELCRO material.

In the patent Gerrans teaches a photographic slide sleeving system in which a self-aligning sleeve for inserting photograph slides into pockets of an elongated web of sleeving material having a plurality of rows with a predetermined number of pockets per row and spaced from one another by a predetermined row spacing distance. The web of sleeving material is supported for movement in a direction perpendicular to the rows of pockets by a chassis base. Figure 6 shows that photograph slides (22) supported by gate (100) and guide bar (98) will fall



Art Unit: 1743

downward to an insertion area (134) when the gate is opened. The slides are supported in the insertion area above the surface of chassis base member (106) by Velcro strips (136, column 8, lines 10-23 and column 12, lines 37-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a VELCRO type of material to support the slides in the Meyer holder because as shown by Gerrans the VELCRO material can be used to support slides rather than its normal function as a fastener.

8. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record fails to teach or fairly suggest the structure of claim 24.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to mechanisms for holding slide materials in a holder.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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